

General

Title

Epilepsy: all female patients of childbearing potential (12 to 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.

Source(s)

American Academy of Neurology. Epilepsy update: quality measurement set. St. Paul (MN): American Academy of Neurology (AAN); 2014. 83 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of all female patients of childbearing potential (12 to 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.

Rationale

Epilepsy is associated with reduced fertility, increased pregnancy risks, and risks for malformations in the infant. Treatment of seizures with anti-seizure medications may alter hormone levels, render oral contraceptives less effective and may interfere with embryonic and fetal development. Certain anti-seizure medications may have specific malformation risks. Folic acid supplementation, monotherapy for epilepsy, using lower doses of medication when possible, and proper obstetrical, prenatal and pre-pregnancy care all should be discussed with the patient so they understand the risks involved and how to

mitigate these risks.

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

If a woman with epilepsy is of childbearing potential and receives oral contraceptives in conjunction with an enzyme inducing antiepileptic drug (AED), then decreased effectiveness of oral contraception should be addressed (higher doses of the oral contraceptive, alternative birth control methods, or change AED) (Pugh et al., 2007).

Patients with epilepsy should receive an annual review of information including topics such as: ... contraception, family planning, and how pregnancy and menopause may affect seizures (Pugh et al., 2007).

Women with epilepsy (WWE) should be counseled that seizure freedom for at least 9 months prior to pregnancy is probably associated with a high rate (84% to 92%) of remaining seizure-free during pregnancy (Harden et al., "Obstetrical complications," 2009).

WWE who smoke should be counseled that they possibly have a substantially increased risk of premature contractions and premature labor and delivery during pregnancy. There is possibly a substantially increased risk of premature contractions and premature labor and delivery during pregnancy for WWE who smoke (Harden et al., "Obstetrical complications," 2009).

Counseling of WWE who are contemplating pregnancy should reflect that there is probably no increased risk of reduced cognition in the offspring of WWE not taking AEDs (Harden et al., "Vitamin K," 2009).

To reduce the risk of major congenital malformations (MCMs), avoidance of the use of valproate (VPA) during the first trimester of pregnancy, if possible, may be considered, compared to the use of phenytoin (PHT) or lamotrigine (LTG) (Harden et al., "Vitamin K," 2009).

In order to enable informed decisions and choice, and to reduce misunderstandings, women and girls with epilepsy and their partners, as appropriate, must be given accurate information and counselling about contraception, conception, pregnancy, caring for children and breastfeeding, and menopause (National Institute for Health and Clinical Excellence [NICE], 2012).

Information about contraception, conception, pregnancy, or menopause should be given to women and girls in advance of sexual activity, pregnancy or menopause, and the information should be tailored to their individual needs. This information should also be given, as needed, to people who are closely involved with women and girls with epilepsy. These may include her family and/or carers (NICE, 2012).

All healthcare professionals who treat, care for, or support women and girls with epilepsy should be familiar with relevant information and the availability of counselling (NICE, 2012).

Discuss with women and girls of childbearing potential (including young girls who are likely to need treatment into their childbearing years), and their parents and/or carers if appropriate, the risk of AEDs causing malformations and possible neurodevelopmental impairments in an unborn child.

Assess the risks and benefits of treatment with individual drugs. There are limited data on risks to the unborn child associated with newer drugs. Specifically discuss the risk of continued use of sodium valproate to the unborn child, being aware that higher doses of sodium valproate (more than 800 mg/day) and polytherapy, particularly with sodium valproate, are associated with greater risk. (Evidence comes from three systematic reviews; one review focused on incidence of malformation and the other two on child neurodevelopmental outcomes. No individual randomized controlled trials (RCTs) were reviewed. This recommendation was also based on GDG consensus opinion.) (NICE, 2012).

In women of childbearing potential, the possibility of interaction with oral contraceptives should be discussed and an assessment made as to the risks and benefits of treatment with individual drugs (NICE, 2012).

In girls of childbearing potential, including young girls who are likely to need treatment into their childbearing years, the possibility of interaction with oral contraceptives should be discussed with the child and/or her carer, and an assessment made as to the risks and benefits of treatment with individual drugs (NICE, 2012).

In women and girls of childbearing potential, the risks and benefits of different contraceptive

methods, including hormone-releasing intrauterine devices (IUDs), should be discussed (NICE, 2012). If a woman or girl taking enzyme-inducing AEDs chooses to take the combined oral contraceptive pill, guidance about dosage should be sought from the summary of product characteristics (SPC) and current edition of the British National Formulary (BNF) (available from the [BNF Web site](#)) (NICE, 2012).

Women and girls with epilepsy need accurate information during pregnancy, and the possibility of status epilepticus and sudden death in epilepsy (SUDEP) should be discussed with all women and girls who plan to stop AED therapy (NICE, 2012).

Opportunity for Improvement

In 2013, the AAN tested its Women with Epilepsy of Childbearing potential measure and evidence of a gap in care remains. Data from the testing project showed that on average less than 40% of women received counseling about epilepsy and how its treatment may affect contraception and pregnancy (MN Community Measurement, 2013). Additionally, the QQuality Indicators for Epilepsy Treatment in adults (QUIET) study demonstrated that only 34% of female patients receive counselling on aspects of epilepsy care specific to women (neurologist alone=32.88%; shared [neurologists and primary care]=44.83%; and primary care alone=11.11%) (Pugh et al., 2011).

For babies whose mothers take seizure medication, the risk of birth defects is 4% to 8% compared with 2% to 3% for all babies (Epilepsy Foundation, n.d.). Despite the availability of practice guidelines, knowledge about the use of seizure medications during pregnancy was low with less than half of neurologists able to identify which medications were linked to adverse events during pregnancy (Roberts et al., 2011).

Evidence for Rationale

American Academy of Neurology. Epilepsy update: quality measurement set. St. Paul (MN): American Academy of Neurology (AAN); 2014. 83 p.

Epilepsy Foundation. Pregnancy issues. [internet]. Landover (MD): Epilepsy Foundation; [accessed 2014 Feb 25].

Harden CL, Hopp J, Ting TY, Pennell PB, French JA, Hauser WA, Wiebe S, Gronseth GS, Thurman D, Meador KJ, Koppel BS, Kaplan PW, Robinson JN, Gidal B, Hovinga CA, Wilner AN, Vazquez B, Holmes L, Krumholz A, Finnell R, Le Guen C. Practice parameter update: management issues for women with epilepsy--focus on pregnancy (an evidence-based review): obstetrical complications and change in seizure frequency. Report of the Quality Standards Subcommittee [trunc]. Neurology. 2009 Jul 14;73(2):126-32. [22 references] [PubMed](#)

Harden CL, Pennell PB, Koppel BS, Hovinga CA, Gidal B, Meador KJ, Hopp J, Ting TY, Hauser WA, Thurman D, Kaplan PW, Robinson JN, French JA, Wiebe S, Wilner AN, Vazquez B, Holmes L, Krumholz A, Finnell R, Shafer PO, Le Guen C. Practice parameter update: management issues for women with epilepsy--focus on pregnancy (an evidence-based review): vitamin K, folic acid, blood levels, and breastfeeding. Report of the Quality Standards Subcommittee [trunc]. Neurology. 2009 Jul 14;73(2):142-9. [45 references] [PubMed](#)

MN Community Measurement. Women with epilepsy draft testing report. Minneapolis (MN): MN Community Measurement; 2013 Dec 18.

National Institute for Health and Clinical Excellence (NICE). The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Jan. 117 p. (Clinical guideline; no. 137).

Pugh MJ, Berlowitz DR, Montouris G, Bokhour B, Cramer JA, Bohm V, Bollinger M, Helmers S, Ettinger A, Meador KJ, Fountain N, Boggs J, Tatum WO 4th, Knoefel J, Harden C, Mattson RH, Kazis L. What constitutes high quality of care for adults with epilepsy. *Neurology*. 2007 Nov 20;69(21):2020-7. [40 references] [PubMed](#)

Pugh MJ, Berlowitz DR, Rao JK, Shapiro G, Avetisyan R, Hanchate A, Jarrett K, Tabares J, Kazis LE. The quality of care for adults with epilepsy: an initial glimpse using the QUIET measure. *BMC Health Serv Res*. 2011;11:1. [PubMed](#)

Roberts JI, Metcalfe A, Abdulla F, Wiebe S, Hanson A, Federico P, JettÃ© N. Neurologists' and neurology residents' knowledge of issues related to pregnancy for women with epilepsy. *Epilepsy Behav*. 2011 Oct;22(2):358-63. [PubMed](#)

Primary Health Components

Epilepsy; patient counseling; epilepsy treatment; contraception; pregnancy

Denominator Description

All females of childbearing potential (12 to 44 years old) with a diagnosis of epilepsy (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Female patients or caregivers counseled at least once a year about how epilepsy and its treatment may affect contraception OR pregnancy (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Importance of Topic

Epilepsy data is lacking. In 2012, the Institute of Medicine released *Epilepsy across the Spectrum: Promoting Health and Understanding*, detailing epilepsy research disparities and highlighting specific areas where further research is needed, including the extent of epilepsy, consequences, comorbid conditions and outcomes of epilepsy (England et al., 2012). The following statistics only touch on the magnitude of epilepsy given lack of research and stigma:

It is estimated 2.2 million people in the United States are diagnosed with epilepsy, and 150,000 new cases of epilepsy are diagnosed in the United States annually (England et al., 2012).

Epilepsy prevalence might be underestimated because of underreporting associated with

repercussions and stigma in disclosing epilepsy (Kobau et al., 2012).

Common comorbidities among people with epilepsy include somatic (i.e., fractures, asthma, diabetes, and heart disease), neurological (i.e., stroke, Alzheimer's disease, autism spectrum disorders, chronic pain), and mental health conditions (i.e., mood disorders, attention deficit hyperactivity disorders, anxiety disorders, suicidality) (England et al., 2012; Kobau et al., 2008).

It is estimated the number of people with epilepsy who die of sudden unexpected death in epilepsy (SUDEP) range from 1 of every 10,000 who are newly diagnosed to 9 of every 1,000 candidates for epilepsy surgery (England et al., 2012).

People with epilepsy are more likely to be unemployed or unable to work, have low annual household incomes, be obese and physically inactive, and to smoke (England et al., 2012; Kobau et al., 2008).

People with epilepsy have poorer overall health status, impaired intellectual and physical functioning, a greater risk for accidents and injuries, and negative side effects from seizure medications (Fountain et al., 2011; England et al., 2012; Kobau et al., 2008).

It is estimated the annual direct medical cost of epilepsy in the United States is \$9.6 billion. This estimate does not include community service costs or indirect costs from losses in quality of life and productivity (England et al., 2012).

Opportunities for Improvement

Additional data on opportunities for improvement and gaps in care specific to the epilepsy measures can be located in the updated epilepsy measures.

A review of 261 patient responses using the PatientsLikeMe survey system indicated a gap remains between recommended care detailed in the 2009 epilepsy measurement set and the care delivered to patients with epilepsy (Wicks & Fountain, 2012).

The Institute of Medicine noted several gaps in care and opportunities for improvement, including 1) timely referrals and access to treatments, 2) epilepsy care and prevention, 3) education of persons with epilepsy and their families, and 4) the stigma of epilepsy (England et al., 2012).

Surgery continues to be heavily underutilized as a treatment for epilepsy, with significant disparities by race and insurance coverage (Englot et al., 2012).

Evidence for Additional Information Supporting Need for the Measure

American Academy of Neurology. Epilepsy update: quality measurement set. St. Paul (MN): American Academy of Neurology (AAN); 2014. 83 p.

England MJ, Liverman CT, Schultz AM, Strawbridge LM. Epilepsy across the spectrum: promoting health and understanding. 1st ed. Washington (DC): The National Academies Press; 2012.

Englot DJ, Ouyang D, Garcia PA, Barbaro NM, Chang EF. Epilepsy surgery trends in the United States, 1990-2008. *Neurology*. 2012 Apr 17;78(16):1200-6. [PubMed](#)

Fountain NB, Van Ness PC, Swain-Eng R, Tonn S, Bever CT Jr, American Academy of Neurology Epilepsy Measure Development Panel and the American. Quality improvement in neurology: AAN epilepsy quality measures: Report of the Quality Measurement and Reporting Subcommittee of the American Academy of Neurology. *Neurology*. 2011 Jan 4;76(1):94-9. [PubMed](#)

Kobau R, Luo YH, Zack MM, et al. Epilepsy in adults and access to care--United States, 2010. *MMWR Morb Mortal Wkly Rep*. 2012 Nov 16;61(45):909-13. [PubMed](#)

Kobau R, Zahran H, Thurman DJ, Zack MM, Henry TR, Schachter SC, Price PH, Centers for Disease Control and Prevention (CDC). Epilepsy surveillance among adults--19 States, Behavioral Risk Factor Surveillance System, 2005. *Morb Mortal Wkly Rep Surveill Summ*. 2008 Aug 8;57(6):1-20. [PubMed](#)

Wicks P, Fountain NB. Patient assessment of physician performance of epilepsy quality-of-care measures. *Neurol Clin Pract*. 2012 Dec;2(4):335-42. [PubMed](#)

Extent of Measure Testing

The new epilepsy measures are being made available without any prior testing. The American Academy of Neurology encourages testing of this measurement set for feasibility and reliability by organizations or individuals positioned to do so.

Evidence for Extent of Measure Testing

American Academy of Neurology. Epilepsy update: quality measurement set. St. Paul (MN): American Academy of Neurology (AAN); 2014. 83 p.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory/Office-based Care

Hospital Outpatient

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

Age 12 to 44 years

Target Population Gender

Female (only)

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Person- and Family-centered Care

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Data Collection for the Measure

Case Finding Period

Unspecified

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Patient/Individual (Consumer) Characteristic

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions

All females of childbearing potential (12 to 44 years old) with a diagnosis of epilepsy

Note: Refer to the original measure documentation for International Classification of Diseases, Ninth Revision (ICD-9), International Classification of Diseases, Tenth Revision (ICD-10), and Current Procedural Terminology (CPT) Evaluation and Management (E/M) service codes.

Exclusions

Unspecified

Exceptions

Patients diagnosed with menopause or surgically sterile.

Patient has a diagnosis of neurodevelopmental disorder, encephalopathy, hydrocephalus, brain injury, or cerebral palsy.

Patient has a diagnosis of severe cognitive impairment or severe intellectual disability.

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Female patients or caregivers counseled* at least once a year about how epilepsy and its treatment may affect contraception OR pregnancy

**Counseling* should include a discussion about folic acid supplementation, contraception, potential anti-seizure medications effect(s) on pregnancy, safe pregnancies, and breastfeeding.

Exclusions

Unspecified

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Electronic health/medical record

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Measure #6: counseling for women of childbearing potential with epilepsy.

Measure Collection Name

Epilepsy Quality Measurement Set

Submitter

American Academy of Neurology - Medical Specialty Society

Developer

American Academy of Neurology - Medical Specialty Society

Funding Source(s)

American Academy of Neurology

Composition of the Group that Developed the Measure

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American Association of Neuroscience Nurses: Mona Stecker, DNP, NP-BC, CNRN, SCRNP

American Board of Internal Medicine: Sharon M. Hibay, RN, DNP

American Clinical Neurophysiology Society: Susan T. Herman, MD

American College of Emergency Physicians: J. Stephen Huff, MD

American Epilepsy Society: Gabriel U. Martz, MD

American Society of Neuroradiology/American College of Radiology: Marvin Nelson, MD

Child Neurology Society: Inna Hughes, MD, PhD

Citizens United for Research in Epilepsy: Tracy Dixon-Salazar, PhD

Epilepsy Foundation: Janice M. Buelow, RN, PhD

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Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Endorser

American Epilepsy Society - Medical Specialty Society

Child Neurology Society - Medical Specialty Society

Epilepsy Foundation - Medical Specialty Society

Date of Endorsement

American Epilepsy Society: 2013 Jul 29

Child Neurology Society: 2014 Jul 29

Epilepsy Foundation: 2014 Aug 7

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2014 Jan

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

Unspecified

Measure Status

This is the current release of the measure.

This measure updates previous versions:

American Academy of Neurology (AAN). Epilepsy physician performance measurement set. St. Paul (MN): American Academy of Neurology (AAN); 2009 Aug 10. 50 p.

Fountain NB, Van Ness PC, Swain-Eng R, Tonn S, Bever CT Jr, American Academy of Neurology Epilepsy Measure Development Panel and the American. Quality improvement in neurology: AAN epilepsy quality measures: Report of the Quality Measurement and Reporting Subcommittee of the American Academy of Neurology. Neurology. 2011 Jan 4;76(1):94-9.

Measure Availability

Source available from the [American Academy of Neurology \(AAN\) Web site](#) .

For more information, contact AAN at 201 Chicago Avenue, Minneapolis, MN 55415; Phone: 800-879-1960; Fax: 612-454-2746; Web site: www.aan.com .

NQMC Status

This NQMC summary was completed by ECRI Institute on December 16, 2011. The information was verified by the measure developer on January 30, 2012.

This NQMC summary was updated by ECRI Institute on January 6, 2016. The information was not verified by the measure developer.

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Production

Source(s)

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